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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/092,066 | 03/04/2002 | Preeti G. Lal | PF-0460-2 CIP | 1365 |

27904 7590 03/09/2004

INCYTE CORPORATION
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| EXAMINER |
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ROBINSON, HOPE A

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| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,066

Applicant(s)

LAL ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 1, drawn to a human PINCH protein homolog, classified in class 530, subclass 350.
 - II. Claims 2-3, 5, 7 and 13-14, drawn to a purified antibody that specifically binds PINCH and compositions, classified in class 530, subclass 387.9+.
 - III. Claim 4, drawn to a method of making a polyclonal antibody, classified in class 424, subclass 184.1.
 - IV. Claim 6, drawn to a method of preparing a monoclonal antibody, classified in class 435, subclass 451.
 - V. Claim 8, drawn to a method for using an antibody for immunopurification, classified in class 530, subclass 415.
 - VI. Claims 9-12, drawn to a method for using an antibody to detect expression of a protein, classified in class 435, subclass 7.8+.
 - VII. Claims 15-16, drawn to a method for treating prostatic adenocarcinoma/cancer, classified in class 424, subclass 130.4.
 - VIII. Claim 17, drawn to a purified agonist, classified in class 530, subclass 350.
 - IX. Claim 18, drawn to a purified antagonist, classified in class 530, subclass 350.
2. The inventions are distinct, each from the other because of the following reasons:

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The protein of Invention I is related to the antibodies of Invention II by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The protein of Invention I, the antibody of Invention II, the agonist of Invention X and the antagonist of Invention XI are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP§ 806.04, MPEP§ 806.04). In the instant case, the different inventions have different biological structures, different modes of operation and different functions. For example, an agonist stimulates/induces where an antagonist inhibits.

Invention I is unrelated to the methods of Inventions III-IV and V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP§ 808.01)). In the instant case the protein of Invention I, is not made by or used in the methods of Inventions III-IV and V-VII.

The product of Invention VIII is unrelated to the methods of Inventions III-IV and V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP

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§ 806.04, MPEP§ 808.01)). In the instant case the agonist of Invention VIII, is not made by or used in the methods of Inventions III-IV and V-VII.

The product of Invention IX is unrelated to the methods of Inventions III-IV and V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP§ 808.01)). In the instant case the antagonist of Invention IX, is not made by or used in the methods of Inventions III-IV and V-VII.

The product of Invention II and the methods of Inventions III-IV and V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in materially different processes of using the products for example, the antibody can be used as vaccine.

The methods of Inventions III-VII are patentably distinct because the methods are directed to different method steps, products and end points. For example the method of Invention III makes a polyclonal antibody and the method of Invention IV makes a monoclonal antibody, while the method of Inventions V and VI are methods of using the antibodies.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Furthermore, the inventions have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, election of a single group for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

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patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. A telephone restriction requirement was not made in this application due to an explicit request by Incyte and their policy of not making elections in response to telephonic restriction requirements.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

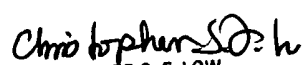
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner


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SUPERVISORY PATENT EXAMINER
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